DEPTH OF BIOLOGY

B. PHARMACY

8 SEM PRACTICE QUESTIONS

QUALITY CONTROL AND STANDARDIZATION OF HERBALS

DEPTH OF BIOLOGY

Unit I **10 hours**

Basic tests for drugs – Pharmaceutical substances, Medicinal plants materials and dosage forms

WHO guidelines for quality control of herbal drugs.

Evaluation of commercial crude drugs intended for use

DEPTH OF BIOLOGY

2/3 MARKS

1. Define crude drugs with an example.
2. What is the significance of WHO guidelines in herbal drug quality control?
3. Mention two basic tests used for evaluating pharmaceutical substances.
4. What are dosage forms? Give two examples.
5. State the purpose of evaluating commercial crude drugs.

DEPTH OF BIOLOGY

5/7 MARKS

1. Explain the importance of WHO guidelines for quality control of herbal drugs.
2. Describe the steps involved in the evaluation of crude drugs intended for use.
3. Write short notes on medicinal plant material testing.
4. Discuss the significance of basic tests for pharmaceutical substances.
5. Explain any five parameters used for quality control of herbal drugs.

DEPTH OF BIOLOGY

10/15 MARKS

1. Describe in detail the basic tests used for pharmaceutical substances, medicinal plant materials, and dosage forms.
2. Explain the WHO guidelines for quality control of herbal drugs.
3. Write a detailed note on the evaluation process of commercial crude drugs intended for use.
4. Discuss the role of standardization in ensuring the quality of herbal drugs.
5. Illustrate the importance of quality assurance in herbal medicine production using WHO guidelines.

DEPTH OF BIOLOGY

Unit II **10 hours**

Quality assurance in herbal drug industry of cGMP, GAP, GMP and GLP in traditional system of medicine.

WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines
WHO Guidelines on GACP for Medicinal Plants.

DEPTH OF BIOLOGY

2/3 MARKS

1. Define cGMP.
2. What is GAP in the context of herbal drugs?
3. Write the full form of GLP.
4. What does quality assurance mean in the herbal drug industry?
5. Mention one WHO guideline related to medicinal plants.

DEPTH OF BIOLOGY

5/7 MARKS

1. Discuss the role of cGMP in the herbal drug industry.
2. Explain the importance of Good Agricultural Practices (GAP) in herbal medicine production.
3. Write a short note on WHO Guidelines on GACP for medicinal plants.
4. Compare GMP and GLP in terms of their application in herbal drug industries.
5. Explain the significance of quality assurance in traditional systems of medicine.

DEPTH OF BIOLOGY

10/15 MARKS

1. Describe in detail the quality assurance systems (cGMP, GAP, GMP, GLP) used in the herbal drug industry.
2. Discuss WHO Guidelines on current Good Manufacturing Practices (cGMP) for Herbal Medicines.
3. Explain WHO Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants.
4. Analyze the role of quality assurance in ensuring the safety and efficacy of herbal drugs in traditional medicine.
5. Elaborate on the differences and importance of GMP, GLP, and GAP in the herbal drug manufacturing process.

DEPTH OF BIOLOGY

Unit III **10 hours**

EU and ICH guidelines for quality control of herbal drugs.

Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines

DEPTH OF BIOLOGY

2/3 MARKS

1. Expand ICH.
2. What is the focus of EU guidelines in herbal drug quality control?
3. Mention one research guideline for herbal medicine safety evaluation
4. Define ICH guidelines.
5. State the purpose of quality control in herbal drugs.

DEPTH OF BIOLOGY

5/7 MARKS

1. Write short notes on ICH guidelines for herbal medicines.
2. Discuss the importance of EU guidelines in herbal drug regulation.
3. Explain the role of research guidelines in evaluating the safety of herbal medicines.
4. Describe the safety and efficacy testing of herbal drugs.
5. Discuss the regulatory aspects of herbal medicines under EU and ICH frameworks.

DEPTH OF BIOLOGY

10/15 MARKS

1. Describe in detail the EU and ICH guidelines for quality control of herbal drugs.
2. Explain the research guidelines for evaluating the safety and efficacy of herbal medicines.
3. Analyze the importance of international guidelines (EU and ICH) in standardizing herbal drug quality.
4. Discuss the impact of regulatory guidelines on the global trade of herbal medicines.
5. Compare and contrast EU and ICH guidelines regarding herbal medicine quality and safety.

Unit IV **08 hours**

Stability testing of herbal medicines.Application of various chromatographic techniques in standardization of herbal products.

Preparation of documents for new drug application and export registration

GMP requirements and Drugs & Cosmetics Act provisions.

DEPTH OF BIOLOGY

2/3 MARKS

1. What is stability testing?
2. Name two chromatographic techniques used for herbal drug analysis.
3. Define GMP requirements.
4. Mention one document required for new drug registration.
5. Write the full form of GACP.

DEPTH OF BIOLOGY

5/7 MARKS

1. Explain the purpose of stability testing in herbal medicines.
2. Describe the role of chromatographic techniques in herbal drug standardization.
3. Write short notes on document preparation for herbal drug export.
4. Discuss GMP requirements for herbal medicines.
5. Explain the importance of the Drugs & Cosmetics Act in herbal drug regulation

DEPTH OF BIOLOGY

10/15 MARKS

1. Describe the process and importance of stability testing of herbal medicines.
2. Discuss various chromatographic techniques used in the standardization of herbal products.
3. Explain the steps involved in preparing documents for new drug application and export registration.
4. Write a detailed note on GMP requirements and their role in herbal medicine quality assurance.
5. Elaborate on the Drugs & Cosmetics Act provisions relevant to herbal drugs.

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Unit V **07 hours**

Regulatory requirements for herbal medicines.

WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems

Comparison of various Herbal Pharmacopoeias.

Role of chemical and biological markers in standardization of herbal products

DEPTH OF BIOLOGY

2/3 MARKS

1. Define pharmacovigilance.
2. What is a pharmacopoeia?
3. Name one chemical marker used in herbal drug standardization.
4. State one regulatory requirement for herbal medicines.
5. Mention the role of WHO in herbal medicine safety monitoring.

DEPTH OF BIOLOGY

5/7 MARKS

1. Discuss the regulatory requirements for herbal medicines.
2. Write a short note on WHO guidelines for pharmacovigilance of herbal medicines.
3. Compare any two Herbal Pharmacopoeias.
4. Explain the role of chemical markers in the standardization of herbal products.
5. Describe the significance of biological markers in herbal drug quality control.

DEPTH OF BIOLOGY

10/15 MARKS

1. Explain the regulatory requirements for herbal medicines and their importance in global trade.
2. Describe WHO guidelines for safety monitoring of herbal medicines in pharmacovigilance systems.
3. Compare and contrast various Herbal Pharmacopoeias in terms of their standards and scope.
4. Elaborate on the role of chemical and biological markers in the standardization of herbal products.
5. Discuss the importance of pharmacovigilance in ensuring the safety and efficacy of herbal medicines.